

DEC 17 2004

**510(k) Summary for
MD-6W Wireless Critical Data Viewer**

1. SPONSOR

The MicroOptical Corporation
33 Southwest Park
Westwood, MA

Contact Person: Paul Zavracky, Ph.D., President
Telephone: 781-326-8111

Date Prepared: October 20, 2004

2. DEVICE NAME

Proprietary Name: MD-6W Wireless Critical Data Viewer
Common/Usual Name: Head-mounted display system
Classification Information:

Head-mounted display systems have been classified as Class II devices under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Laparoscope and accessories	GCJ	876.1500	General Surgery

3. PREDICATE DEVICES

The MD-6W Wireless Critical Data Viewer is substantially equivalent to MicroOptical's MD-6 Critical Data Viewer, 510(k) No. K040244.

4. DEVICE DESCRIPTION

The MD-6W Wireless Critical Data Viewer contains a mobile viewer (consisting of an LCD display unit, non-prescription safety glasses, and a control box with signal converter and lithium-ion rechargeable battery) and a base station that connects via cable to a patient monitor. The LCD display unit is mounted on the non-prescription safety glasses and is connected via a four-foot cable to the control box. The control box receives signal via wireless telemetry from the base station. The battery is recharged using a separate battery charger.

5. INTENDED USE

The MD-6W Wireless Critical Data Viewer is intended to display patient vital signs in such a way that the data is continuously in a medical specialist's field of view. A typical application would be to view the vital signs of a patient undergoing surgery.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The MD-6W Wireless Critical Data Viewer is similar to the predicate device in terms of indication, display format, field of view, and focal range.

7 PERFORMANCE TESTING

The MD-6W Wireless Critical Data Viewer has been subjected to standard optical, electrical, firmware, and mechanical tests to demonstrate the acceptability of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

The MicroOptical Corporation
c/o Mr. Daniel J. Dillon
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K042923

Trade/Device Name: MD-6W Wireless Critical Data Viewer
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 20, 2004
Received: October 20, 2004

Dear Mr. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MD-6W Wireless Critical Data Viewer

Indications for Use:

The MD-6W Wireless Critical Data Viewer is intended to display patient vital signs in such a way that the data is continuously in a medical specialist's field of view. A typical application would be to view the vital signs of a patient undergoing surgery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042823